Medacta International

510(k) Summary

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AUG 15 2013

Contact Person: Mr. Adam Gross
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Date Prepared: February 5, 2013

DEVICE INFORMATION

Trade/Proprietary Name: GMK Hinge
Common Name: Total Knee Prosthesis
Classification Name: Prosthesis Knee, Femorotibial, Constrained, Cemented, Metal/Polymer

21 CFR 888.3510
Class II
Device Product Code: KRO

Predicate Devices:

510(k)	Product	510(k) Holder	Clearance Date
K003504	RT-Plus	Plus Orthopedics	5/11/2001
K013385	NexGen Rotating Hinge Knee	Zimmer	1/9/2002
K002552	Modular Rotating Hinge Knee	Stryker/Howmedica	11/13/2000
K101815	Enduro RHK	Aesculap	12/20/2010
K896048	S-ROM/NOILES	Depuy	03/14/1990

Product Description

The GMK Hinge System is a hinged-knee system for total knee replacement. The GMK Hinge femoral component is designed to preserve bone stock. The hinge-post system is comprised of the hinge post and the hinge post extension and has been developed in order to reduce the impingement with the patellar tendon and provide mechanical resistance. There is a UHMWPE bushing between the femoral component and the hinge post in order to avoid contact between metal parts. The tibial component has an asymmetric design to provide coverage of the bone after tibia resection. The surface is mirror polished and the holes for the tibial augmentations are on the bottom. The UHMWPE tibial insert is fixed to the tibial component through a screw and is designed to provide high rotational control and a high varus/valgus constraint. The femoral and tibial augments allow the surgeon to selectively fill bone deficiencies and to aid in restoring the joint line. The fixation between the augmentations and the femoral component or tibial tray is assured by a screw fixation. The GMK Hinge provides two solutions for the patella prosthesis: an inset patella and a resurfacing patella. The GMK Hinge System would be used most often in patients with poor bone quality or marked bone loss, and in these circumstances, extension stems are helpful to obtain a stable construct. An extension stem in combination with the right offset connector provides intramedullary femoral and tibial fit and fill.

Indications for Use

The GMK HINGE® knee prosthesis is designed for cemented use in total knee arthroplasty when the preoperative diagnosis of the joint determines that the bone and stability situation require the implantation of a constrained prosthesis.
The GMK HINGE® knee system is indicated in the following cases:

- Severely painful and/or disabled joint as a result of arthritis, traumatic arthritis, rheumatoid arthritis or polyarthritis associated with bone loss and/or severe joint instability
- Considerable loss of function of the knee joint
- High-grade joint destruction requiring additional stabilization with stems and reconstruction of bone defects with metal augmentation
- Failure of a primary prosthesis (e.g. infection, loosening)
- Former revision arthroplasty

- Post traumatic loss of joint configuration
- Avascular necrosis of femoral condyle

Tibial augmentations are to be screwed to the tibial baseplate with both of the two provided fixing screws.
When a GMK HINGE® implant is used it is mandatory to implant both the femoral and tibial components with an extension stem.

Comparison to Predicate Devices

The indications for use, design features, and materials of the subject device are substantially equivalent to those of the predicate devices.
The design features of both the GMK Hinge and the predicates are a constrained, rotating knee prosthesis that have similar sizes and shapes and are intended to be used for cemented use only.
The GMK Hinge and the predicates use the same materials:
CoCrMo (ISO 5832-4)
UHMWPE (ISO 5834-2 Type 1)
Ti6Al4V (ISO 5832-3)
CoCrMo (ISO 5832-12)
M30NW (ISO 5832-9)

The fundamental scientific technology of the modified devices has not changed relative to the predicate devices. The safety and effectiveness of the GMK Hinge are adequately supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification.

Performance Testing

The GMK Hinge was compared to the worst case of the predicate devices.
GMK Hinge was tested according to the following standards:

- ISO 21534
- ISO 7207-1
- ASTM F1800
- ASTM F2083-11
- ASTM F1223-08

The comparison to predicate devices and the mechanical testing performed demonstrate that the GMK Hinge does not introduce any issues in regards to safety and effectiveness.

Conclusion:
Based on the above information, the GMK Hinge can be considered as substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 15, 2013

Medacta International SA
% Medacta United States of America
Mr. Adam Gross
Director of Regulatory and Quality
4725 Calle Quetzal, Unit B
Camarillo, California 93012

Re: K130299
Trade/Device Name: GMK Hinge
Regulation Number: 21 CFR 888.3510
Regulation Name: Knee joint femorotibial metal/polymer constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KRO
Dated: June 20, 2013
Received: June 21, 2013

Dear Mr. Gross:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For Erin D Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130299

Device Name: GMK Hinge

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Prescription Use ____x____ (21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.
Division of Orthopedic Devices